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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,896	12/11/2001	Xuanchuan Yu	LEX-0280-USA	2399

24231 7590 05/14/2004

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EXAMINER	
MOORE, WILLIAM W	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,896	YU ET AL.	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's Amendment filed February 6, 2004, has been entered and it is agreed that the new claims 5-13 introduce no new matter where each embodiment described by the original claims 1-4 and the new claims 5-13 are disclosed in the specification. No requirement for restriction need be stated with respect to the originally-claimed and the newly-claimed subject matters. As noted in the Office communication mailed October 3, 2003, claims 1-4 [were] examined together" because "a search of the prior art identified documents relevant to all four claims present in the application" where the nucleic acid sequence set forth in SEQ ID NO:3 described by the new claim 5 is a splicing variant of the nucleic acid sequence set forth in SEQ ID NO:1 described by the original claim 1, lacking nucleotide sequence regions from position 901 through position 963, inclusive, and from position 1140 through position 1506, inclusive. Thus products of claims 4 and 5 encode a protease of SEQ ID NO:4 that shares the amino acid sequence of the protease of SEQ ID NO:2 encoded by products of claims 1-3 through position 300 but, due to a shift in reading frame, diverges thereafter with a carboxyl-proximal amino acid sequence of 61 amino acids, rather than the further 202 amino acids of SEQ ID NO:2. Like the original claims 1-4, the new claims 5-13 present no issues of enablement as to making, or of an indefinite description, under the first paragraph and second paragraphs of 35 U.S.C. § 112 because the scope of the intended subject matter is clear and the artisan can prepare both the generic expression vectors of claims 6-9 and the generic host cells of claims 10-13. The Amendment filed February 6, 2004, does not overcome the rejections of record for lack of utility and for lack of enablement as to use under, respectively, under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, stated in the Office communication mailed October 3, 2003, for the reasons set forth below.

Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-13 are rejected, essentially for reasons of record, under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

This is essentially the rejection of record but, in view of Applicant's Amendment filed February 6, 2004, is extended to include the new claims 5-13. This is because a lack of a specific utility of a claimed nucleic acid sequence perforce entails a lack of utility of recombinant expression vectors and host cells that comprise it where neither the vectors nor the host cells can be used to make an encoded product that has a specific utility. Applicant's arguments at pages 4-12 in the Response filed February 6, 2004, have been fully considered but are not persuasive. Applicant first suggests that a disclosure in the specification that the presence of polymorphisms in the region encoding the first 300 amino acids specified by both SEQ IDs NOs:1 and 3, particularly where it has not yet been shown that all naturally-occurring coding nucleic acid sequence regions have polymorphisms, indicates that the claimed nucleic acid sequences have utility as forensic markers. While this argument is pertinent to claims 1, 3 and 5 that require specific nucleotide sequences, it is not considered applicable to subject matters of claims 2, 4 and 6-13 where the claimed products have no property that might permit them to serve the alleged utility. It is noted that Applicant's argument does not allege that the non-isocoding polymorphisms, present in either of SEQ IDs NOs: 1 and 3 and disclosed at page 17 of the specification, have any particular degree of representation in any human population, thus the alleged forensic utility is considered to be generic in that it is no more specific than any other polymorphism(s) anywhere else in the sequences of the human chromosomes, or the sequence of chromosome 1

which page 17 of the specification suggests to be the location of the gene that is the source of the transcript(s) cloned by Applicant. There is no agreement with Applicant's allegation that polymorphisms Applicant identifies in the nucleotide sequences disclosed herein have any particular significance due to a relative lack of polymorphisms in other human genes. Instead, any apparent absence of sequence polymorphisms among some reported genes is considered to reflect the absence of detection of native polymorphisms to date. It is further noted that Applicant's alleged forensic utility of the two disclosed non-isocoding polymorphisms is indistinguishable from the use of both isocoding polymorphisms in genes and polymorphisms in non-coding regions of genes.

Insofar as the specification fails to disclose such an alleged utility, e.g., at pages 1 and 8 where utilities of nucleotide sequences are discussed, it is clear that such alleged utility was not contemplated, and was not disclosed or suggested, at the time Applicant filed the instant application. An undisclosed utility cannot be considered to be a specific and substantial utility Applicant conveyed to the public at the time application was filed.

Unlike the appellate decisions that Applicant cites, the invention claimed herein is not an article of manufacture, as in *Carl Zeiss,* nor a pharmaceutical composition where a specific utility had been disclosed for the component considered by the appellate panel in *Brana*, but a "molecule", see claims 1-5, that is a heteropolymer, a linear array of four nucleotides arranged in a varying sequence that, for the claimed sequences, encodes a polypeptide, and it is the claimed molecule that must have a specific and substantial utility. Although Applicant believes that evidence should be gathered and cited in a rejection for lack of utility to demonstrate that an alleged utility is non-specific, insubstantial or incredible, it is clear that there is a lack of evidence in the record that claimed nucleic acid sequences have either a specific or substantial utility. An assertion of utility must be based on some utility specific to the claimed molecule.

A claimed invention must posses a specific, substantial and credible *in vitro* or *in vivo* utility, but the instant application cannot identify any specific, substantial, utility for the invention described by the claims known to the inventors at the time the application was filed as evidenced by the disclosure of the specification. No requirement for a "unique" utility is maintained in this rejection, only a requirement that a utility specific to a claimed molecule be disclosed to the public so that something may be achieved specifically with a claimed nucleic acid sequence. Applicant additionally argues that the specification discloses a specific *in vitro* for at least an isolated nucleic acid sequence having the nucleotide sequences of SEQ IDs NOs:1 and 3 in the preparation of nucleic acid sequence microarrays or "gene chips" and in mapping at least the human chromosome 1 but these cannot be specific utilities, and are only suggestions of a generic utility, where the specification discloses no significance for the expression of the claimed nucleic acid sequences and where any other nucleic acid sequences of similar size from chromosome 1 will serve the same purpose. Where the specification discloses no biological or physiological significance for the splicing that Applicant alleges to confer a specific utility, this argument similarly has no merit. It is agreed that the threshold for utility is not high and that utility is conferred by disclosure of an "identifiable benefit" provided by a claimed invention but the specification and Applicant's argument cannot, together, demonstrate a specific, i.e., identifiable, benefit the public could be provided that is identified in the disclosure. The rejection of record is therefore sustained as to claims 1, 3 and 5, to which Applicant's arguments, broadly construed, apply and sustained as well as to claims 2, 4 and 6-13 that cannot benefit from the arguments Applicant presents in traversal of the rejection of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are also rejected, essentially for reasons of record, under the first paragraph of 35 U.S.C. § 112, where the rejection of record is extended to include the new claims 5-13 in view of Applicant's Amendment filed February 6, 2004. Applicant's arguments at pages 12 and 13 in the Response filed February 6, 2004, have been fully considered but are not persuasive. Specifically, since the record does not show that the inventions described by claims 1-5 have a specific or substantial utility, indeed are not supported by either a specific asserted utility or a well established utility for the reasons set forth above, neither may the recombinant expression vectors and host cells of claims 6-13 that comprise such nucleic acid molecules be considered to be supported by either a specific asserted utility or a well established utility, and one skilled in the art clearly would not know how to **use** the claimed invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
April 29, 2004

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER